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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,606	12/27/2001	Hidemitsu Nishida	1110-0306P	9102
2292	7590	11/20/2003	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			PATEL, SUDHAKER B	
			ART UNIT	PAPER NUMBER
			1624	18

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/026,606

Applicant(s)

NISHIDA ET AL

Examiner

Sudhaker B. Patel, D.Sc.Tech.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 19-29 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☒ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 10
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

### DETAILED ACTION

1. Applicants' communication paper # 9 dated 10/14/03 is acknowledged. Applicants have **cancelled old claims 1-18** and presented **new claims 19-29** while confirming that the subject matter of cancelled claims 6-9, 13 has been deleted from the above stated new claims. Applicants have presented their counter proposal for the restriction/election. Applicants have not confirmed the election of a group from the newly proposed groups, and have not also elected the species as required by the earlier Office communication paper # 8 dated 9/12/03.
2. The examiner regrets the typo error of reciting -CH- as -CH<sub>2</sub>-. Applicants' arguments and remarks have been considered favorably, and found persuasive for the regrouping of the inventions.
3. **Examiners' position regarding restriction/election:** Upon reviewing this application further, examiner found that the working examples as recited in specification pages 177-301 and in Table of pages 302-315, mostly consist of Y = Oxygen or NH or NMe; X = N; m = zero; l = one; n = 1 i.e. tricyclic combination of **6:5:6 rings** which are actually made and tested. It is believed that there is no support for the other combinations as claimed herein e.g. Tricyclic heterocycles having: **6:6:6 or 6:7:6 or 6:7:7 combinations**. Therefore, Examiner initiated the discussion with applicants (see interview summary dated 11/18/03, attached with this paper). Applicants desired a written document for discussion with their overseas clients to reply this action. Based on above data the restriction/election has been compacted as follows.

***Election/Restrictions***

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims (in part) 19-29, drawn to tricyclic-spiro compounds of generic formula (I), wherein X is Nitrogen, Y = oxygen atom, NH or imino group optionally substituted, integer m = zero, integer l = 1, integer n = 1 i.e. 3-fused rings combination as 6-membered saturated piperidine-50membered saturated hetero-ring with Y – O or imino-6-membered 1,4-diaza-piperazine consisting of; (1). Piperidine-1,4-diaza-7-oxa-spirobicyclo[4,3,0]-nonanone or (2). Piperidine- 1,4,7-triaza-spirobicyclo[4,3,0] nonan-2-one, classified in **class 544**, subclasses 358,380,384; utility **class 514**, subclasses 248,245,250,252.15,252.13.
  - II. Claims(in part)19-29, and subject matter of old non-elected/cancelled claims 6-9,13 drawn to compopunds/intermediates not included in invention of Group I, their composition and a method of use(where applicable). e.g. compounds for Formula (I) wherein X = -CH- i.e. forming 6-membered Benzene; Y = -NH-, O, S, SO or SO<sub>2</sub>; integers m, n forming a ring with 7 members wherein 1, 3-diaza- or 1,3 oxazo- or 1,3-thiaza-7-membered ring is fused with 6-membered ring 1 N or alternatively, when integer n = 2 or 3, forming a 7- or 8-membered 1,4-diaza-heterocycle which is fused with 5- or 6- or 7-membered heterocycles having Y variable, classified in various classes. e.g. a few of which are, compound **class 540**, utility **class 514**, subclasses various depending on the nature

of the variables. If this group is elected, further restriction/election will be required as there are many unknowns. Additionally, a single species (from the actual working example (with all variables exactly and definitely known) must be disclosed.

5. The inventions are distinct, each from the other because of the following reasons:

The groups as presented above, are distinct inventions, each from the other because of the following reasons: The compounds of Groups I-II are drawn to:

- (1). Structurally diverse compounds that are made and used independently of each other;
- (2). Compounds are separately classified;
- (3). Classes will require separate literature searches;
- (4). Compounds are not art recognized equivalents, and additionally,
- (5). The groups lack unity of invention(see MPEP 803.02).

Based on above stated data i.e. (1) - (5), it is believed that claim 1 also lacks unity of invention. The chemical structures are different with multiple values of the variables. e.g. when variable A is Hydrogen atom the compound is unsubstituted B or X variable; when A is a saturated 5- or 6- membered cyclic hydrocarbon group it is cyclopentane or cyclohexane, and when A is a saturated or unsaturated 5- or 6- membered heterocyclic group there are many more unknown possibilities. Note, claim 1 remains silent about the exact nature, size of the ring, and make up of the heteroatoms(s) in a heterocycle together with the exact point of attachment with carbon atom of the main core/bridge.

6. Inventions I-II are related as product, its composition, and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case Compounds of WO 9616940 as well as Das et al(U.S.P. 5691356) can be also used for the utility as claimed herein.

7. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. Claims 19,22,23, 24,25,26,27-28 are generic to a plurality of disclosed patentably distinct species comprising (where applicable) (1). A variable having meanings H, Hydrocarbon, 5 or 6-membered heterocycle, -NH<sub>2</sub>, imidoyl; (2). B = absent or forming a CO or S, So SO<sub>2</sub> or alkylene; (3). X is N or CH<sub>2</sub> i.e. forming cyclohexane or piperidine cores; (4). Integers  $m + l = 1$  i.e. forming a 5-membered ring with Y (= O/S/SO/SO<sub>2</sub>/NH) and N; (5). Integers  $m + l = 2$  i.e. forming a 6-membered ring; (6). Integers  $m + n = 3$  i.e. forming a 7-membered ring; (7). Integers  $m + n = 4$  i.e. forming an 8-membered ring respectively. Additionally, the components T & Q, and values of integer  $n = 0-2$  will provide further many compounds, which are not chemical equivalents of each other.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from the working example, even though this requirement is traversed.

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. A telephone call was made to Dr. Ms.Armstrong on 11/17/03 to request an oral election to the above restriction requirement, but did not result in an election being made as applicants desired a written document for discussion(s) with their clients abroad.(See enclosed interview summary).

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**Additional formalities to be completed by applicants:**

14.1. This application as received by the examiner did not contain a computer readable disc for the Sequence listing to be approved by the people concerned. Therefore, the

same has not been recorded by the Office. Applicants are urged to act accordingly to avoid unnecessary delays at a latter stage prior to allowance of this application.

14.2. It is believed that applicants have not recited/provided the correct PCT International Application NO. \_\_\_\_\_ as well as its English version/translation. It will be necessary for the examination because the **instant application is a continuation in part of the said International Application NO. \_\_\_\_\_**, with a filing date \_\_\_\_\_, published on \_\_\_\_\_. Applicants are urged to provide the same to the office for a proper, thorough, and complete examination by the examiner.

14.3. Additionally, the U.S. Application Sr. NO. 1045728, filed on 6/25/03, which is a national stage application and is a 371 of PCT/JP01/11656, filed 12/28/2001 will raise other issues. e.g. double patenting. See copy of the claims enclosed with this communication.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is 703 308 4709. The examiner can normally be reached on 6:30 to 5:00 pm. Monday-Thursday.

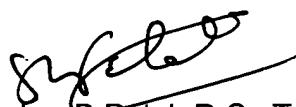
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on 703 308 4716 or Sr. Examiner Mr. Richard Raymond at 703 308 4523.


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The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.

  
Sudhaker B. Patel, D.Sc.Tech.  
November 18, 2003.

  
MUKUND SHAH  
SUPERVISORY PATENT  
EXAMINER  
ART UNIT 1624